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February 2, 2016

Honorable Alison J. Nathan  
United States District Judge  
Thurgood Marshall United States Courthouse  
40 Foley Square, Room 906  
New York, New York 10007

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Re: *Braintree Laboratories, Inc. v. Breckenridge Pharmaceutical, Inc.*  
Case No.: 12-cv-6851-AJN

Dear Judge Nathan:

We represent Defendant Breckenridge Pharmaceutical, Inc. ("Breckenridge") in this action. This letter responds to the letter submitted by counsel for Plaintiff Braintree Laboratories, Inc. ("Braintree") on February 1, 2016. (Dkt. 104.)

Braintree's letter lists various other companies that have filed ANDAs or NDAs directed to SUPREP, apparently in an attempt to suggest that this Court's action on Breckenridge's Motion for Summary Judgment would not result in Breckenridge moving closer to providing the public with a generic product. Braintree is incorrect.

First, as Breckenridge detailed in its letter dated June 16, 2015, it is likely that Novel Laboratories, Inc. ("Novel") forfeited any 180-day market exclusivity to which it might have been entitled. (See Dkt. 75.) Novel failed to obtain tentative approval for its ANDA product within the requisite time period, and Breckenridge is not aware of any reason that the delay in approval of Novel's ANDA would be excused. See 21 U.S.C. § 355(j)(5)(D)(i)(IV); Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144, 126 Stat. 993, § 1133(a) (July 9, 2012). Consequently, Breckenridge believes that when the FDA acts on its ANDA, it may grant final approval, allowing Breckenridge an opportunity to immediately launch its generic product.

Second, even if Novel did not forfeit its exclusivity by failing to receive timely tentative approval, Breckenridge still needs a decision from this Court to launch its product. A subsequent ANDA filer such as Breckenridge who obtains "a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken [finding] that the patent is invalid or not infringed" triggers a 75-day deadline for the first-filer to launch its product or lose its 180-day



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exclusivity. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA). Such a final decision is an alternative means of clearing the path to allow Breckenridge to launch its product, for which a decision by this Court on Breckenridge's Motion is the necessary first step.

The fact that other ANDA filers have settled or agreed to stay their cases simply means that other than Novel's appeal of an adverse decision by the District Court of New Jersey, Breckenridge's Motion is the only imminent challenge to Braintree's marketing exclusivity. This is a compelling reason for this Court to promptly issue its ruling on Breckenridge's Motion, rather than a reason for further delay, as urged by Braintree.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Steven Lieberman', written over the typed name.

Steven Lieberman

cc: All counsel of record

**CERTIFICATE OF SERVICE**

I hereby certify that on February 2, 2016, a true and correct copy of the foregoing **LETTER FROM STEVEN LIEBERMAN TO JUDGE NATHAN** was filed through the Court's Electronic Filing System (ECF), and was served electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

/s/ Erik van Leeuwen  
Erik van Leeuwen  
Litigation Operations Manager  
Rothwell, Figg, Ernst & Manbeck, P.C.